

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Bradley P. Glassman et al.

Application No.: **Continuation of 10/127,963**

Group Art Unit: N/A

Filed: January 14, 2004

Examiner: Not Yet Assigned

For: **METHOD OF TREATING ONYCHOMYCOSIS
WITH UREA AND AN ANTIOXIDANT**

INFORMATION DISCLOSURE STATEMENT

MS Patent Application
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO/SB/08a/b are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO/SB/08a/b based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior

art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith. It is further understood that the Examiner will consider information that had been cited by or submitted to the U.S. Patent and Trademark Office in a prior application relied on under 35 U.S.C. § 120. 1138 OG 37, 38 (May 19, 1992).

Applicants have checked the appropriate boxes below.

- 1. This Information Disclosure Statement is being filed within three months of the U.S. filing date OR before the mailing date of a first Office Action on the merits. No statement under 37 C.F.R. § 1.97(e) or fee is required.
- 2. This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection or Notice of Allowance.
 - a. I hereby state that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1).
 - b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to my knowledge after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2).

c. Attached is our Check No. _____ in the amount of \$ _____ in payment of the fee under 37 C.F.R. § 1.17(p).

3. This Information Disclosure Statement is being filed more than three months after the U.S. filing date and after the mailing date of a Final Rejection or Notice of Allowance, but before payment of the Issue Fee. It is hereby requested that the Information Disclosure Statement be considered. Attached is our Check No. _____ in the amount of \$ _____ in payment of the fee under 37 C.F.R. § 1.17(i).

a. I hereby state that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1).

b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to my knowledge after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2).

4. Relevance of the non-English language document(s) is discussed in the present specification.

5. The document(s) was/were cited in a corresponding foreign application. An English language version of the foreign search report is attached for the Examiner's information.

6. A concise explanation of the relevance of the non-English language document(s) appears below:

7. The Examiner's attention is directed to co-pending U.S. Patent Application Nos. 10/127,963, filed April 22, 2002, and 10/370,666, filed February 20, 2003, which are directed to related technical subject matter. The identification of this U.S.

Patent Application is not to be construed as a waiver of secrecy as to that application now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited application and the art cited therein during examination.

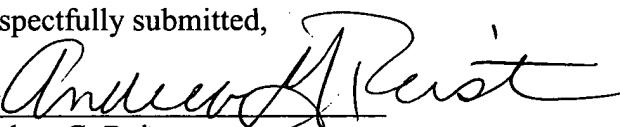
☒ 8. Copies of the documents were cited by or submitted to the Office in Application No. 10/127,963, filed April 22, 2002, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d).

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO/SB/08a/b, and to indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 50-0740, referencing Docket No. 025562.0012-US01.

Dated: January 14, 2004

Respectfully submitted,

By 
Andrea G. Reister

Registration No.: 36,253
COVINGTON & BURLING
1201 Pennsylvania Avenue, N.W.
Washington, DC 20004-2401
(202) 662-6000

Substitute for form 1449A/B/PTO				Complete if Known	
				Application Number	Continuation of 10/127,963
				Filing Date	January 14, 2004
				First Named Inventor	Bradley P. Glassman
				Art Unit	N/A
				Examiner Name	Not Yet Assigned
Sheet	1	of	2	Attorney Docket Number	025562.0012-US01

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No.	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
AA	US-4,295,567-B1	09-09-1997	Knudsen		
AB	US-4,581,351	04-08-1986	Berke et al.		
AC	US-5,340,836	08-23-1994	Reinhard et al.		
AD	US-5,407,958	04-18-1995	Heath et al.		
AE	US-5,445,823	08-29-1995	Hall et al.		
AF	US-5,525,635	06-11-1996	Moberg		
AG	US-5,573,765	11-12-1996	Reinhard et al.		
AH	US-5,707,635	01-13-1998	Deckner et al.		
AI	US-5,853,732	12-29-1998	Munden		
AJ	US-5,919,470	07-06-1999	Valdez et al.		
AK	US-5,968,533	10-19-1999	Porter et al.		
AL	US-6,262,117-B1	07-17-2001	Sefton		
AM	US-6,281,239-B1	08-28-2001	Bradley Pharmaceuticals, Inc.		
AN	US-6,673,842	01-06-2004	Bradley Pharmaceuticals, Inc.		

FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)			
BA	WO-WO 96/19186		06-27-1996	Johnson & Johnson Consumer Products, Inc.	
BB	WO-WO 98/23152		06-04-1998		

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. **CITE NO.: Those patent(s) or publication(s) which are marked with an double asterisk (**) next to the Cite No. are not supplied because they were previously cited by or submitted to the Office in a prior application relied upon in this application for an earlier filing date under 35 U.S.C. 120. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			T ²
	CA	Friedman-Bimbaum, R. et al., "Treatment of onychomycosis: A randomized, double-blind comparison study with topical bifonazole-urea ointment alone and in combination with short-duration oral griseofulvin," International Journal of Dermatology, 36(1): 67-69 (1997) (Abstract).			
	CB	Gennaro et al., editors, Remington's Pharmaceutical Sciences, 18th ed., 767-768 and 1329 (1990).			
	CC	Lucy, J.A., "Functional and Structural Aspects of Biological Membranes: A Suggested Structural Role for Vitamin E in the Control of Membrane Permeability and Stability," Annals of the New York Academy of Sciences, 203: 4-11 (December 18, 1972).			
	CD	Scharffetter-Kochanek, K. et al., "Photoaging of the skin from phenotype to mechanisms," Experimental Gerontology, 35(3): 307-316 (May 2000).			
Examiner Signature			Date Considered		

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	C ontinuation of 10/127,963
<i>(Use as many sheets as necessary)</i>				Filing Date	January 14, 2004
				First Named Inventor	Bradley P. Glassman
				Art Unit	N/A
				Examiner Name	Not Yet Assigned
Sheet	2	of	2	Attorney Docket Number	025562.0012-US01

	CE	Thiele, J.J., "The Antioxidant Network of the Stratum corneum," Curr. Probl Dermatol., 29: 26-42 (2001).	
	CF	U.S. Patent Application Serial No. 09/998,537, filed November 28, 2001 entitled "Antioxidant Dermatological Composition."	

¹EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	
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